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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,015	09/26/2005	Peter Forsell	2333-139	7845
23117 7590 08/31/2010 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER GILBERT, SAMUEL G				
ART UNIT		PAPER NUMBER		
3735				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/530,015

**Applicant(s)**

FORSELL, PETER

**Examiner**

Samuel G. Gilbert

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 and 36-114 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 - "claim 1, 3," in line 1 is unclear, further as set forth in the claim 35 of claims of 4/1/2005 the claim was amended to depend from only claim 1. Now the claim is written to depend from claims 1 and 3 without a proper amendment.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte (4,190,040).

Claim 1 - the examiner is taking element -3- to be an implantable pump, elements -8- - -10- and -12- - -14- teach a wall forming a chamber, first wall

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portion includes elements -12- - -14- and a second wall portion -8- - -10- which is displaceable relative to the first wall to pump fluid into implant -1-. The second wall portion -8- - -10- is self sealing, column 2 lines 23-37. Element -5- is a penetrating needle. The applicant argues that housing 3 is non-expandable and thus the second wall does not move. In response it is the examiner's position that housing 3 can be non-expandable but that does not preclude second wall, elements -8-, -9- and -10- from being compressed towards the first wall and pumping the fluid from within element -3- into inflatable envelope -1-. The second wall is formed from silicone rubber which is inherently flexible and capable of being compressed. The second wall is further designed to operate under high pressure as set forth in at least column 2 lines 12-22 and therefore is capable of being compressed without failure or rupture as suggested by the applicant.

Claim 2 - the membrane is inherently manually displaceable, it is formed from silicone rubber.

Claim 3 - figure 3 shows the membrane in a first position having a first volume and when depressed the membrane would press to the first wall portion and the chamber would have a smaller volume.

Claim 4 - the membrane is flexible and takes the shape of a semi-sphere (dome), column 2 lines 34.

Claim 8 - the chamber is substantially emptied when the membrane is in the second position.

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Claim 9 - the membrane includes a first layer -9- and a second layer -8-.

The first layer having better strength properties and the second layer having better sealing properties.

Claim 10 the first layer(silicone rubber) is harder than the second layer(silicone gel).

Claim 11 - the second layer is between the first layer and the chamber.

Claim 12 - element -10- is a third layer harder than the second layer.

Claim 13 - the silicone gel layer inherently has a Shore hardness of less than 20.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 14 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (5,562,598, hereinafter Whalen) in view of Schulte (4,190,040).

Whalen teaches an artificial sphincter having an infusion port and separate magnetically operated pump. The pump is activated by placing an external magnet close to the pump. The internal magnet drives the pump membrane and locks it in place until an external magnet is removed.

Schulte teaches a pump that also functions as an infusion port but does not teach locking means.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the magnetic drive/locking means taught by Whalen with the pump/port of Schulte to produce a port/pump with a magnetic drive/locking mechanism as taught by Whalen. Further, the combined pump/port then would replace the separate pump and port taught by Whalen to form an implantable sphincter with an implantable magnetically driven/locked pump/port. Such an arrangement would produce the benefit of requiring a single implantable element in place of two separate elements pump -30- and port -160-. This arrangement would reduce the possibilities of complications by shortening surgery time and reducing the number of implanted objects.

Claim 6 - the membrane is "pushed" by magnetic forces and locked in the second position.

Claim 14 - use of the device of the combination would produce a pump/port used in an incontinence device.

### ***Allowable Subject Matter***

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest an implantable pump

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as claimed including a locking device which is released upon pushing the membrane and the membrane resumes it first position.

### ***Response to Arguments***

Applicant's arguments filed 6/18/2010 have been fully considered but they are not persuasive.

Regarding Shulte the applicant argues that element -3- is an implantable housing but not a pump. It is the examiner's position that because the structure of Shulte is identical to the structure claimed by the applicant that whatever name given to the components is irrelevant. Further, The examiner agrees that Shulte does not teach a method of compressing the second wall to pump the fluid into envelope -1- however, the structure is clearly capable of being compressed to pump the fluid. Further, the applicant is not claiming a method only an apparatus and the apparatus of Schulte is capable of performing the intended use of pumping as set forth in the claim language.

Regarding the rejections over Whalen et al in view of Schulte The applicant argues that compression the housing of Schulte would break the housing and cause leakage without providing any evidence. A non-expandable device may not expand and get larger but is not precluded from being compressed. Further, the second wall is formed from silicone designed to handle high pressure as set forth in Schulte, therefore compression should not cause any damage to the second wall.

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***Allowable Subject Matter***

Claim 7 is allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/  
Primary Examiner, Art Unit 3735